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Comparison of ISO/IEC 17025 with the NUPIC Audit Checklist

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May 2003

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Introduction

A meeting was held on August 5, 2002, in San Diego, Ca, during the National Conference of Standards Laboratories International (NCSLI) Conference and Symposium, to discuss Nuclear Regulatory Commission (NRC) recognition of the use of accredited commercial calibration laboratories as suppliers of commercial grade calibration services to regulated utilities. In attendance were:

Name	*Affiliation*
Dick Pettit	Sandia National Laboratories
Clint Eldridge	Pacific Gas & Electric
Larry Nielsen	Southern California Edison
Jack Ferris	Sleeping Bear Metrology
John Ragsdale	Tennessee Valley Authority (TVA)
Roxanne Robinson	American Association for Laboratory Accreditation (A2LA) (National Cooperation for Laboratory Accreditation (NACLA) President)
Tony Anderson	Guildline Instruments (NACLA Board member)
Mary Saunders	National Institute of Standards and Technology (NIST) (NIST representative to NACLA Board)
Doug Faison	NIST/National Voluntary Laboratory Accreditation Program (NVLAP)

The purpose of the meeting was to map out a strategy for approaching the NRC concerning the issue of calibration laboratory accreditation and the National Cooperation for Laboratory Accreditation (NACLA). The intent is to gain NRC endorsement of laboratory accreditation based on internationally accepted standards as a means of qualifying calibration service providers as suppliers to nuclear power facilities.

One of the group's defined tasks was to develop a gap analysis between the internationally accepted requirements for laboratory accreditation and NRC requirements. Copies of several NRC documents were obtained and, after a review of those documents, and on the advice of industry experts, it was decided that the comparison should be conducted using the audit requirements of the Nuclear Utilities Procurement Issues Committee (NUPIC), which most accurately reflect the requirements of **10CFR50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants**.

This document is, therefore, a comparison of NRC requirements, as defined by the **NUPIC Commercial Grade Survey Checklist for Calibration Services,** with the internationally accepted requirements for laboratory accreditation, contained in **ISO/IEC 17025:1999, General requirements for the competence of testing and calibration laboratories**. This document does not specifically discuss the process of laboratory accreditation and/or the process of peer evaluations of laboratory accreditation bodies for the purpose of mutual recognition. The left column gives the verbatim text from the NUPIC Checklist, the center column is the relevant text from 17025, and the right column provides commentary on the comparison between the two.

Basis for the Comparison

The NUPIC Checklist is a set of 18 Methods of Verification spread over fourteen Sections of the checklist as follows:

Section I - Training/Qualifications
Section II - Calibration System Description
Section III - Contract Requirements
Section IV - Adequacy of Measurement Standards
Section V - Calibration Procedures
Section VI - Environmental Controls
Section VII - Intervals of Calibration
Section VIII - Calibration Status
Section IX - Calibration Traceability
Section X - Subcontractor Calibration
Section XI - Storage and Handling
Section XII - Out of Tolerance/Corrective Action
Section XIII - Calibration System Adequacy
Section XIV - Records

The language of the Methods of Verification appears to be taken from, or is at least very similar to, the requirements of **ANSI/NCSL Z540-1-1994, the American National Standard for Calibration - Calibration Laboratories and Measuring and Test Equipment - General Requirements**. For each of the 18 Methods of Verification, there is reference to the relevant Z540 requirements section or clause(s).

For comparison purposes, only sections 4 and 5 of 17025 are relevant since Sections 1 through 3 contain the Scope of the Standard, References, and Definitions, but no requirements. However, clauses 1.1 and 1.2 of the Scope provide useful guidance as to the applicability of the standard as follows:

17025 clause 1.1	“This International Standard specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.”
17025 clause 1.2	“This International Standard is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification.”

Based on the way the NUPIC Methods of Verification are expressed, it is difficult in some cases to determine what would be considered as acceptable compliance. Without further guidance, compliance may be subject to the interpretation of the requirements by individual auditors. As can be seen in the comparison, ISO/IEC 17025, as implemented through the process of laboratory accreditation, is very specific concerning compliance to the standard.

As previously stated, the focus of this effort is on gaining NRC acceptance of accredited laboratories as suppliers of *commercial grade calibration services* only. Thus, the requirements of **10CFR21; Nuclear Regulatory Commission, Reporting of Defects and Noncompliance**, are not relevant to this comparison.

Conclusions

In the final analysis, the comparison shows that 17025 adequately addresses all but two administrative issues, namely:

1. NUPIC clause 14.1.c.7	"The calibration certificate/report shall include identification of the laboratory equipment/standards used." 17025 does not require this, but does require that records be kept.
2. NUPIC clause 14.1.c.12	"The calibration certificate/report shall include as-found and as-left data." 17025 only requires as-found data to be reported when the device under test is adjusted/repaired.

One additional issue requires explanation. Clause 4.1 of the NUPIC checklist states, in part, "Well defined and documented measurement assurance techniques or uncertainty analyses may be used to verify the adequacy of the measurement process. If such techniques are not used, the collective uncertainty of the measurement standards shall not exceed 25% of the acceptable tolerance for each characteristic being calibrated." This is typically referred to as the four-to-one ratio. The NUPIC Checklist does not specifically require the four-to-one ratio but does allow its use if an uncertainty analysis is not available. 17025 requires an uncertainty analysis to support all measurement results, therefore the four-to-one ratio rule is not applicable.

However, clause 12.6 of **Standard Review Plan (SRP) Section 17.1, Quality Assurance During the Design and Construction Phases Review Responsibilities**, states "Calibration of this equipment should be against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, have an accuracy that assures the equipment being calibrated will be within required tolerance and that the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function is identified." Although the SRP is not a requirements document and uses the term "should" instead of "shall", the four-to-one ratio has become something of a default requirement and industry experts believe this issue should be considered in this comparison.

Each of the three issues noted above can easily be addressed by requiring the utilities to add language to their purchase orders for commercial grade calibration services. For example, to address the four-to-one ratio, the following requirement could be added. "the collective expanded uncertainty of the measurement standards must not exceed 25% of the acceptable tolerance for each characteristic being calibrated." Adding this statement to the purchase order would ensure that an uncertainty statement be provided, as required by 17025, and that the four-to-one ratio required by SRP 17.1 be maintained or exceeded. Similar statements could be added to the purchase order to require that standards used in the calibration process and all as-found and as-left data be reported in the Calibration Certificate/Report.

It should also be noted that 17025 contains many requirements, both management and technical, that are not addressed by the NUPIC checklist and are not included in the comparison. Laboratories accredited to 17025 have more thoroughly addressed those issues necessary to assure competence, capability, and traceability of measurement results.

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Comparison of the NUPIC Commercial Grade Survey Checklist for Calibration Services with ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
Section I - Training/Qualifications 1.1 Verify personnel have sufficient education, training, technical knowledge, and experience for their assigned functions.	5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.	Section 5.2 of 17025 is dedicated to assuring that all personnel are trained and qualified to perform their duties. 17025 identifies management's responsibility to ensure competence of personnel and oversight of trainees.
	5.2.3 The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system.	17025 requires that all personnel, including those under contract, follow the documented quality system.
Review personnel qualification records, which provide the basis for an adequate training and qualification program.	5.2.5 The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.	17025 requires that management assume the responsibility for authorizing specific individuals to perform specific tasks and that appropriate records be kept.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
(continued) Assess continuing training of calibration personnel.	5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory.	17025 specifically requires the lab to have policies and procedures for identifying training needs and that management be responsible.
Section II - Calibration System Description 2.1 Verify that the supplier has established and documented a quality system appropriate to the type, range and volume of calibration activities performed.	4.2.1 The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results.	17025 specifies in detail the requirements for a documented quality system. The entire Section 4 Management Requirements is relevant.
a. Are the calibration supplier's policies and objectives defined?	4.2.2 The laboratory's quality system policies and objectives shall be defined in a quality manual (however named). The overall objectives shall be documented in a quality policy statement. The quality policy statement shall be issued under the authority of the chief executive. It shall include at least the following: a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its clients; b) the management's statement of the laboratory's standard of service; c) the objectives of the quality system; d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and e) the laboratory management's commitment to compliance with this International Standard.	17025, section 4.2 Quality System, requires that policies and objectives be defined, that they be documented in a quality policy statement, and details what is to be included in the policy statement.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
b. Is the quality documentation available for use by calibration personnel?	4.2.1 ....The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.	17025 requires that the quality documentation not only be available for use, but also that it be communicated to and understood by appropriate personnel.
c. Is there an organization chart available?	4.1.5 The laboratory shall e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services; f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations; 4.2.4 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this standard, shall be defined in the quality manual.	17025 requires that the organization be well defined and that interrelationships of all personnel also be specified.
d. Does the quality system document provide for: scope of lab activities, personnel training, procedure control, maintenance of standards, identification and control of discrepancies, internal audits, and reports/records.	4.2.3 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the quality system.	This requirement appears to have been drawn from Z540-1, section 5.2, which states that the quality manual and related documentation shall also include... This requirement was deleted in 17025 because too many labs were incorrectly developing QMs that addressed only the listed elements. 17025, section 4.2 Quality System, requires that **all** elements of the standard be addressed in the QM, including those specified in the NUPIC checklist.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
e. Does quality system document address 10CFR50 Appendix B and 10CFR21? Does supplier accept customer orders with 10CFR21 invoked? (for information purposes only)	Not a specific requirement of 17025. However, the relevant clauses are: 4.2.1 The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities. 4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that: a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2); b) the laboratory has the capability and resources to meet the requirements;	Only commercial grade calibration services are being considered. Therefore, 10CFR21 is not applicable. The NUPIC checklist is designed to address the requirements of 10CFR50 Appendix B. Therefore, it is 17025 in its entirety that is relevant.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
Section III - Contract Requirements 3.1 Verify that deviations/exceptions to customer purchase orders are documented and controlled: a. Exceptions to purchase order discussed/resolved at order entry, prior to work	4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that: a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2); b) the laboratory has the capability and resources to meet the requirements; c) the appropriate test and/or calibration method is selected and capable of meeting the clients' requirements (see 5.4.2). Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the client. 4.4.2 Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract. 4.4.3 The review shall also cover any work that is subcontracted by the laboratory. 4.4.4 The client shall be informed of any deviation from the contract. 4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.	17025 has added a complete section (4.4) that deals with the review of requests, tenders and contracts which specifies in detail the necessary steps to be taken, records to be kept, etc.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
Section V - Calibration Procedures 5.1 Verify procedures are available and are utilized for calibration of M&TE and standards and that they specify: Standard(s) to be used Equipment to be used The required parameter, range, and accuracy of the standard	5.4.1 The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.	Although 17025 is less prescriptive in its requirements for the content of calibration procedures, sufficient attention is paid through the requirements for complete uncertainty analyses to ensure that procedures and supporting equipment used are sufficient to meet the needs of the service provided.
	5.4.2 The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the client and which are appropriate for the tests and/or calibrations it undertakes.	
	5.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use.	
	5.6.1 All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established program and procedure for the calibration of its equipment.	As previously discussed, 17025 requires that all real or potential influences on the uncertainty of measurement results be addressed.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
5.2 Verify that when a device tolerance (range) is not known or specified and an uncertainty (regression) analysis is performed, adequate procedure controls exist to control sampling of data used for the analysis. Assess the rationale/justification for the sampling plan selected.	5.4.1 The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include **sampling**, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data. 5.7.1 The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results. 5.7.3 The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.	This NUPIC requirement appears to be tied to Z540-1, clause 10.5 which addresses when sampling is carried out as part of the calibration method, not when (and if) sample data is used for the uncertainty analysis. In reality, all data used for uncertainty analyses are sample data. Also, an uncertainty of a measurement result is required whether or not the tolerance of the device under test is known or specified. The original requirement came from ISO/IEC Guide 25, which was the basis for Z540-1 and was applicable to both calibration and testing labs. Sampling is a concept employed mostly by test labs where, for example, samples from a batch are tested, but not the entire batch, or where the test is destructive, so that only selected samples are tested. The requirement was left in Z540-1 for those few instances where sampling may be applicable to calibrations. One example is calibration of a roll of thermocouple wire: the entire roll is not tested, but usually three segments of wire are tested: one from each end and one from the middle. The requirement is well covered by 17025 should it be applicable to any calibrations performed where sampling is part of the method.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
5.3 Verify calculations and data transfers are subject to appropriate checks.	5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.	17025 requires that checks be accomplished in a systematic manner.
5.4 Verify when computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage, or retrieval of calibration data, the laboratory ensures that:	5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:	17025 requirements are more prescriptive and are an improvement over Z540-1 and NUPIC requirements.
a. Computer software is documented and adequate for use;	a. computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;	
b. Procedures are established and implemented for protecting the integrity and security of data;	b. procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;	
c. Computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration data.	c. computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.	

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
Section VI - Environmental Controls 6.1 Verify M&TE and standards are calibrated and utilized in an environment controlled to the extent necessary to assure continued measurements of required accuracy (i.e., humidity, temperature, EMI, line voltage, sound/vibration levels, and cleanliness).	5.3.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations. The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented. 5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations. 5.3.3 There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination. 5.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances. 5.3.5 Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.	17025 specifically identifies requirements for documentation of conditions that can affect results and requires that the tests and calibrations are to be stopped when environmental conditions jeopardize the results. 17025 also requires that any influence on the results of measurements attributable to environmental factors be accounted for in the uncertainty analyses.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
Section VII - Intervals of Calibration 7.1 Verify the supplier has a recall system established to assure M&TE and standards are calibrated at established intervals and maintained to assure acceptable accuracy and reliability.	5.6.1 All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established program and procedure for the calibration of its equipment.	While 17025 does not use the term "recall," it does require that the lab have an on-going program and procedure for determining and setting intervals in place.
Section VIII - Calibration Status 8.1 a. Verify M&TE and standards are uniquely identified and labeled to indicate calibration status (minimum calibration date and calibration due date). Where impractical to label the item, the vendor shall provide other suitable means to identify the status of them.	5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.	17025 requires that all equipment be labeled or otherwise identified so that its calibration status and its fitness for purpose can be determined. This includes identification of limitations, etc.
b. Items that are not calibrated to their full range, or have other limitations, shall be identified to that condition.		
c. Also verify that the supplier has controls in place to apply tamper resistant seals to operator accessible controls or adjustments, which if moved, would affect the calibration. The calibration system shall provide instructions for use of the seals and disposition on items whose seals are broken.	5.5.12 Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.	17025 does not require a seal be used but does require that appropriate safeguards be employed.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
Section IX - Calibration Traceability 9.1 Verify that M&TE, calibration standards and reference materials are: Traceable to national, international, or intrinsic standards where available.	5.6.1 General - All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established program and procedure for the calibration of its equipment. 5.6.2.1.1 For calibration laboratories, the program for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (*Système international d'unités*).	17025 requires that all measurement results be traceable to stated references per the accepted definition of the term "traceability" as found in the International Vocabulary of Basic and General Terms in Metrology (VIM: 1993, 6.10) and as adopted by NIST. Furthermore, all recognized accreditation bodies (signatories to the ILAC, APLAC, EA, and/or NACLA MRA) have implementation policies on traceability that follow the ILAC Policy and Guidance documents. Verification of traceability is fundamental to the accreditation process.
Supported by certificates, reports, or data sheets	A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).	17025 specifies the acceptable path(s) of traceability, requires that external calibration labs be able to demonstrate competence, and specifies what, at a minimum, must be included in calibration certificates. Furthermore, all accreditation bodies have requirements to the effect that all calibration services required to support a laboratory's services, must come from national metrology institutes or from accredited labs.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
Where traceability to national, international, or intrinsic standards of measurement is not available, traceability requirements may be satisfied by: a) participation in a suitable program of inter-laboratory comparisons or proficiency testing b) internationally accepted standards in the field concerned. c) suitable reference materials d) ratio or reciprocity type measurements e) mutual consent standards agreed upon by all parties concerned	5.6.2.1.2 There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as: – the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material; – the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned. Participation in a suitable program of interlaboratory comparisons is required where possible.	17025 has provisions for situations where traceability to the SI is not possible. In these cases clients are to be notified up front and service provider labs are required to correlate their results with others making the same measurements.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
Section X - Subcontractor Calibration 10.1 Verify the supplier assures that sub-contractors providing calibration services for their own M&TE and standards are capable of performing the required services in accordance with the documented program (ref. Checklist Item 2.1). Assess established controls for subcontractor capability determined through audits/surveys, source surveillance, history, etc. a) customer notification required when calibration is subcontracted. b) subcontractor capability determined through audits/surveys, source surveillance, history, etc.	4.6.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations. 4.6.2 The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained. 4.6.3 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release. 4.6.4 The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.	Clause 10.1 of the NUPIC checklist appears to be a misinterpretation of the concept of subcontracting as it applies to Z540-1 and 17025. The requirements for subcontracting apply when the laboratory intends to subcontract the service it offers to it's customers. When this happens there are clear rules that must be followed in 17025. When a laboratory has its standards and M&TE calibrated by another laboratory, this does not fall under subcontracting but under purchasing of services. All, or at least most laboratories purchase calibration services from other labs to support the services they offer to their customers. There is no need for the lab to notify the customer when this happens. There are well defined requirements for the purchasing of services and/or supplies in 17025.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
10.2 Where calibration services for customer M&TE/standards are sub-contracted, access controls for: a) customer notification/approval required b) customer requirements imposed on sub-contractor b) subcontractor capability to meet applicable requirements	4.5.1 When a laboratory subcontracts work whether because of unforeseen reasons (e.g., workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g., through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this standard for the work in question. 4.5.2 The laboratory shall advise the client of the arrangement in writing and, when appropriate, gain the approval of the client, preferably in writing. 4.5.3 The laboratory is responsible to the client for the subcontractor's work, except in the case where the client or a regulatory authority specifies which subcontractor is to be used. 4.5.4 The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this standard for the work in question.	17025 requires that subcontracted service providers be competent, that the customer be notified in writing, and that the subcontracting laboratory maintains responsibility for the services provided to its customers. 17025 also requires that a register of qualified subcontractors be maintained which includes evidence of compliance to the standard.
Section XI - Storage and Handling 11.1 Verify M&TE and Standards are handled, stored, and transported in accordance with established laboratory procedures to avoid deterioration or damage, which could affect the calibration of the equipment.	5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.	17025 also requires that, when the subject standard or M&TE becomes a "calibration item", the requirements of section 5.8: "Handling of test and calibration items" apply.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
Section XII - Out of Tolerance/Corrective Action 12.1 Verify the supplier's system provides for customer notification when Laboratory's M&TE/standards and/or customer's M&TE/standards are found to be significantly out-of-tolerance. Evaluate the adequacy of the definition of significant and the associated corrective action measures.	4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the client. The policy and procedures shall ensure that: a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified; b) an evaluation of the significance of the nonconforming work is made; c) corrective actions are taken immediately, together with any decision about the acceptability of the nonconforming work; d) where necessary, the client is notified and work is recalled; e) the responsibility for authorizing the resumption of work is defined.	17025 contains requirements for notification of the customer when there is evidence of non-conforming work. Out-of-tolerance conditions are considered non-conforming work. 17025 also identifies the aspect of recalling non-conforming work from the customer for recalibration when necessary.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
(continued) Also, verify the system provides for the prevention of inaccuracy by detection of deficiencies and timely, positive action for their correction.	4.10 Corrective action 4.10.1 General - The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified. 4.10.2 Cause analysis - The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem. 4.10.3 Selection and implementation of corrective actions - Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence. 4.10.4 Monitoring of corrective actions - The laboratory shall monitor the results to ensure that the corrective actions taken have been effective. 4.10.5 Additional audits - Where the identification of nonconformances or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this handbook, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.13 as soon as possible.	17025 also requires that corrective actions be monitored and that when necessary, additional audits be conducted to ensure the effectiveness of corrective actions taken.

From the NUPIC Checklist	**Relevant requirement(s) of ISO/IEC 17025**	**Comments**
(continued)	4.11 Preventive action 4.11.1 Needed improvements and potential sources of nonconformances, either technical or concerning the quality system, shall be identified. If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformances and to take advantage of the opportunities for improvement. 4.11.2 Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.	17025 implements an additional requirement for the laboratory to identify potential sources of non-conformances and to establish preventive action procedures when necessary.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
Section XIII - Calibration System Adequacy 13.1 Verify the supplier has established and maintains documented procedures to: a) Evaluate the adequacy of the calibration system through internal audits or equivalent oversight to verify compliance with established requirements.	4.13.1 The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this standard. The internal audit program shall address all elements of the quality system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. NOTE: The cycle for internal auditing should normally be completed in one year. 4.13.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify clients in writing if investigations show that the laboratory results may have been affected. 4.13.3 The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded. 4.13.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken. 4.14.1 In accordance with a predetermined schedule and procedure, the laboratory's executive management shall periodically conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements.	17025 contains detailed requirements for internal audits and management reviews. 17025 also requires that auditors be properly trained to conduct audits and independent of the area being audited, where possible.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
b) In addition to internal audits, are internal checks implemented?: 1. statistical techniques 2. proficiency testing/inter-laboratory comparisons 3. use of certified reference materials 4. use of alternate methods for replicating measurements	5.9 Assuring the quality of test and calibration results The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following: a) regular use of certified reference materials and/or internal quality control using secondary reference materials; b) participation in interlaboratory comparison or proficiency-testing programs; c) replicate tests or calibrations using the same or different methods; d) retesting or recalibration of retained items; e) correlation of results for different characteristics of an item. NOTE The selected methods should be appropriate for the type and volume of the work undertaken.	17025 includes a new section specifically on "Assuring the quality of test and calibration results."

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
Section IX - Records 14.1 Verify calibration service is supported by records. These records should include, but are not limited to: a. laboratory equipment/reference standards	5.5.5 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:	17025 includes all requirements of the NUPIC checklist plus a requirement to maintain copies of the manufacturer's instructions.
1. name/description of equipment/standard	2. the identity of the item of equipment and its software;	
2. manufacturer's name, model, serial number, or other unique identification	3. the manufacturer's name, type identification, and serial number or other unique identification;	
3. laboratory location	d. the current location, where appropriate;	
4. calibration status/date information	c. Checks that equipment complies with the specification (see 5.5.2); f. dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;	
5. history of calibrations, maintenance, repairs, damage, modifications	g. the maintenance plan, where appropriate, and maintenance carried out to date;	
6. out of tolerance data	h. any damage, malfunction, modification or repair to the equipment.	
	e. the manufacturer's instructions, if available, or reference to their location;	

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
(14.1) b. calibration personnel 1. training courses 2. prior education/experience 3. qualifications/certifications	5.2.5 The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.	17025 also requires that records of the specific authorizations for certain functions be kept.
c. calibration certificate/report	5.10.2 Test reports and calibration certificates Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:	17025 requires that suppliers of calibration services meet the requirements of the standard. The standard requires certain information be included in calibration certificates/reports. Section 5.10 applies.
1. title, unique identification number	a) a title (e.g., "Test Report" or "Calibration Certificate"); c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;	17025 also requires page identification and end of report identification.
2. calibration laboratory location	b) the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;	17025 requires that the lab and the location where the calibration was conducted be identified, if different.
3. customer name/address/purchase order number	d) the name and address of the client;	17025 does not require the purchase order number to appear on the certificate. It has little relevance to the calibration performed.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
4. unique identification of calibrated equipment	f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;	17025 also requires that a description of and the condition of the calibrated equipment be provided.
5. calibration date	g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration;	17025 also requires the date of receipt where this information is critical.
6. calibration procedure used	e) identification of the method used;	17025 requires that the method of calibration be identified as opposed to simply naming the procedure.
7. laboratory equipment/standards used		Not required by 17025 to be included in the report. 17025 does require that the information be recorded in the laboratory's records.
8. deviations or out-of-tolerance conditions notation	i) the test or calibration results with, where appropriate, the units of measurement; and 5.10.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met. When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference. When statements of compliance are made, the uncertainty of measurement shall be taken into account.	17025 requires that results be reported, good or bad, or that a statement of compliance (or non-compliance) to a metrological specification be made.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
9. collective uncertainty statement	5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results: b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;	17025 requires that an uncertainty of the measurement result be reported and that, where a statement of compliance is made, uncertainty must be accounted for.
10. traceability to national standards statement	c) evidence that the measurements are traceable (see note 2 in 5.6.2.1.1).	17025 requires that the stated reference, usually national standards, be identified.
11. signature/title of laboratory approval person	5.10.2 j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;	17025 requires the signature of the person assuming responsibility for the reported results. Laboratory accreditation defines this as the Approved Signatory.
12. calibration results data (as-found & as-left)	5.10.4.3 When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.	17025 requires reporting of as-found and as-left data only if the calibration item has been adjusted/repaired but records must be maintained of the data at all times.
	Additional reporting requirements of 17025 are as follows: 5.10.2 h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results; k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated. 5.10.4.1 a) the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results;	No equivalent NUPIC requirement.

From the NUPIC Checklist	Relevant requirement(s) of ISO/IEC 17025	Comments
	5.10.4.4 A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the client. This requirement may be superseded by legal regulations. 5.10.5 Opinions and interpretations When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.	
Note: verify that quality program document specifies record retention period; and determine implementation effectiveness.	4.12.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.	17025 requires that the laboratory define its record retention requirements based on the needs of its customers and the relevant regulatory requirements.

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